6. CONCLUSIONS AND POSSIBLE FUTURE RESEARCH

This report includes both descriptive and analytic information that will help understand and improve implementation of the new Medicare drug benefit. As described at the outset, health plans and PBMs may use classification systems as a technical tool simply to organize their formularies, but they do not seem to be essential to plan decisions about which drugs to include on their formularies. In applying the rules determined by the MMA to determine whether plan formularies are adequate, however, the USP classification system has become a critical tool that could have important implications for plans' coverage decisions.

Formulary Decisions

In our analysis, there are 28 classes in the USP classification scheme in which a minimally acceptable formulary would be able to meet the basic CMS rules but leave commonly used drugs uncovered. If plans regularly implemented such minimally acceptable formularies, there would be considerable impact on beneficiaries, either in terms of changing drugs or paying out of pocket to continue taking an off-formulary drug. While plans may have competing incentives to cover additional drugs, these 28 classes may warrant additional review to ensure that beneficiaries' needs will be met.

According to our analysis, even real-world formularies in use today would not meet the CMS tests for adequacy without some adjustments. Presumably, it will not be too difficult for these plans to make the necessary adjustments by adding a few drugs to their formularies, or moving them to lower tiers. However, CMS may also want to pay attention to the classes that were commonly failed by current formularies to ensure that plans are providing adequate access to the drugs that Medicare beneficiaries need.

We also that modeling plans at the drug class level may offer a way to look for risk selection behavior. In the real world formularies we looked at in our model, one plan was cheaper than another for beneficiaries who take only cholesterol-lowering drugs, but more costly for beneficiaries who take other types of drugs. While this is not likely driving enrollee choices in private sector health plans, such situations might lead to risk selection in a situation where beneficiaries are choosing among plans that cover only prescription drugs.

During this project, we identified several questions about how drugs are defined that will have important implications for interpretations of the USP classification system and the CMS rules. Decisions about whether different forms, strengths, and extended-release versions of a drug should be considered as one drug will affect beneficiary access and plan costs. In general, CMS appears to have decided that form, strength, and extended-release cannot be used to create two versions of a drug that would count toward meeting the requirement of two drugs per class. The different versions of a drug can be treated differently, however, in terms of coverage and cost sharing.

We also identified several drugs excluded from the USP system that collectively account for approximately 15% of all utilization by Medicare beneficiaries. While some of these exclusions are for policy reasons, such as drugs not covered by Part D, other exclusions

appear to be oversights. Until such omissions are corrected or justified, these drugs may be less likely to appear on plan formularies.

Unlike any other system that we studied, USP leaves out most combination products, including many that are heavily used. CMS has determined that combination drugs should not count toward the two drugs per class rule. This removes some incentive for plans to include these drugs on their formulary, but retains more incentive for them to continue to cover the single-ingredient drugs in the same categories. Careful analysis of the prevalence of these excluded drugs and their importance in clinical practice may suggest the need for USP's classification scheme to be modified in MMA's second year to better accommodate the needs of Medicare beneficiaries.

USP's decision to classify drugs in multiple categories in some cases but not in others can affect how and whether a formulary meets CMS requirements. A PDP may choose to cover two forms of a particular drug that would enable the formulary to meet CMS standards in a certain class, but disregard the fact that those forms are less commonly prescribed in that class. Continued monitoring of the classes that include drugs listed in multiple categories may help determine whether there are plans attempting to game the classification system in this way.

Beneficiary Impact

The burden on beneficiaries when plans do not cover the drugs they take varies by class. First, since utilization is heavily concentrated in a few categories and classes, formulary decisions for these few groups of drugs can have a broad-ranging impact. Even if a plan meets CMS' minimum rules in these classes, large numbers of beneficiaries may be affected when other drugs are uncovered.

In addition, the substitutability and price of drugs in different classes affects how burdensome coverage decisions are for beneficiaries. Some categories and classes are quite diverse; the rule requiring just two to be covered may not adequately ensure all needs are satisfied. If there are classes where drugs are not easily substitutable, but plans cover only a fraction of the available drugs, beneficiaries may be faced with difficult decisions about whether to change a drug or to pay the full cost of an off-formulary drug. The effectiveness of plans' exceptions processes will be particularly important in these cases. In fact, if drugs in particular classes are frequently the subject of an exception request, it might reveal this type of situation and suggest the need for additional formulary guidance.

Conversely, some categories and classes have just one or a few rarely-used drugs. Lack of coverage for these rarer drugs can still cause a formulary to "fail" the CMS rules. Although these cases may not affect a lot of beneficiaries, the intent is to protect beneficiaries whose drugs are not commonly used when they have no close substitutes for their drugs.

In addition to decisions about whether a drug is on or off a plan's formulary, decisions about cost sharing levels will also be critical to beneficiaries' ability to get the drugs they need and to overall program costs. We provide some indication that the use of coinsurance, compared to flat copayments, retains more differences in prices and thus leads to more switching of drugs. Furthermore, more switching occurs when brands and generics are

assigned different cost sharing amounts. As the amount of switching increases, both total spending and out-of-pocket spending go down. As long as beneficiaries are still receiving drugs that treat their conditions well, this is a win-win-win situation for beneficiaries, plans, and the Medicare program.

However, when beneficiaries decide to pay the full cost to take an off-formulary drug, their cost sharing is considered outside the Part D system. Overall costs go down with tighter formularies, but some of that is at the expense of higher average costs paid by beneficiaries out of their own pockets. While official TrOOP spending will be held at 25% by design under the MMA, total out-of-pocket spending goes up when more drugs are excluded from a formulary. It could be important to track which drugs beneficiaries seek out even though they are off-formulary, to determine whether revisions are needed to the USP system or the formulary rules that would provide better access to the drugs beneficiaries need.

Our results reflect a partially artificial system in which we have held the total number of prescriptions constant. Total spending and out-of-pocket spending may also be affected if the use of cost tiers affects the number of beneficiaries who take a given type of drug. For example, some beneficiaries faced with taking a drug on a higher cost tier or an off-formulary drug may fail to fill a prescription rather than paying the higher cost out of pocket. Conversely, beneficiaries may start using additional prescription drugs given the newly available insurance coverage. In this case, total program spending may not drop as predicted, even if new users pick the lowest-cost alternative.

Potential for Future Research

Follow-up projects could address a number of issues, including risk selection, the implications of CMS's "non-discrimination" requirements, and the results of using actual Part D formularies. Some future work could offer additional baseline analysis of how the various drug categories differ. As shown for the classes included in the model, we have built the capability of using the database to show the balance of generic and brand drugs by category, as well as average prices – both overall and separately for generics and brands. If more information on the relative substitutability of drugs in different categories becomes available, this information could be incorporated in this baseline analysis as well.

Although we touched upon the possibility of risk selection in this project, a more comprehensive and detailed study that focused solely on the potential for risk selection by drug class would be much more insightful. A study that systematically analyzed the "non-discrimination" requirements would help policymakers better understand and anticipate the specific implications of such regulation, such as what percent of drug volume could be off-formulary in each drug class when minimum coverage requirements are met.

Finally, a study that analyzed actual PDP formularies would reveal likely volume and on- and off-formulary spending amounts. Analysis could be performed at the class level, providing more detailed descriptive and "switchability" measures, giving policymakers an indication of likely outcomes and potential problems that could accompany the full implementation of the MMA.